



# DECLARATION OF CONFORMITY

## Regarding Medical Device Regulation (EU) 2017/745



**Manufacturer:** Foshan Oscar Medical Instrument Co., Ltd.

**Address:** NO.3 Huayue Road, Nanhai National Eco-industrial park,  
Danzao town, Nanhai district, Foshan city, Guangdong,  
China

**EC Representative:** SUNGO Europe B.V.

**Address:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:** Rollator

**Model:** TRA01, TRA02, TRA02C, TRA03, TRA04, TRA08, TRA11, TRA14, TRA18,  
TRA21, TRA22, TRA25, TRA32M, TRA34, TRB01

**SRN:** \_\_\_\_\_ **Basic UDI-DI:** \_\_\_\_\_


**Classification:** Class I

**Rule:** Rule 1, Annex VIII, Regulation (EU) 2017/745

**Conformity Assessment Procedure:** Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2012	EN ISO 15223-1: 2016
EN 1041:2008+A1:2013	ISO 10993-1: 2018
EN ISO 10993-5: 2009	EN ISO 10993-10: 2013
ISO 11199-2:2005	

**Signature:** 

**Name / Position:** Luo Yaoqiu / GM

**Date:** 2020-11-10

**Place:** GuangDong / China

